

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
CORPUS CHRISTI DIVISION**

JACLYN KELLEY, Individually, and JOSHUA
KELLEY, Individually, and as Personal
Representatives of the Estate of A. K.,

Plaintiffs,

v.

FISHER-PRICE, INC.; MATTEL, INC.; AMY
RENEE WILLIAMS a/k/a AMY MORIN,

Defendants.

Case No. 2:21-CV-231

ORAL ARGUMENT REQUESTED

**DEFENDANTS MATTEL, INC.'S AND FISHER-PRICE, INC.'S
MOTION TO EXCLUDE OR LIMIT THE OPINIONS AND TESTIMONY OF ERIN
MANNEN, PH.D. AND INCORPORATED MEMORANDUM OF LAW**

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TABLE OF CONTENTS

	Page
INTRODUCTION	1
FACTUAL BACKGROUND.....	2
I. The Rock ‘n Play Sleeper	2
II. The December 14, 2015 Incident.....	3
III. Erin Mannen’s Expert Report and Background.....	4
LEGAL STANDARD.....	6
ARGUMENT	8
I. Mannen Admits She Is Not Qualified to Testify on Any Medical Issues, Including Medical Causation, And Should Be Precluded from Offering Any Testimony and Opinions She Has Disclaimed.....	8
II. Mannen’s Testimony and Opinions Are Neither Reliable nor Relevant and Should Be Excluded.....	10
A. Mannen Did Not Employ Any Scientifically Reliable Methodology in Reaching Her Opinions.....	10
B. Mannen’s Speculative Hypotheses and Opinions Are Based on Factual Assumptions Without Evidentiary Support, And There Is Too Great an Analytical Gap Between Her Study Data and Her Litigation Opinions.	11
1. Mannen’s Testimony Based on Her Speculative “Chin-To-Chest” Hypothesis Must Be Excluded.....	12
2. Mannen’s Testimony Based On Her Speculative 90°-Head Turn/“Carbon-Dioxide Rebreathing” Theory Must Be Excluded.	14
3. Mannen’s Testimony Based on Her Speculative “Decreased Oxygenation” Hypothesis Must Be Excluded.	16
4. Mannen’s Testimony Based on A Mysterious RNPS that She Received Second-Hand from an Unknown Source Must Be Excluded.....	17
III. Mannen’s Failure to Provide the Underlying Data Upon Which Her Opinions Are Based Violates Rule 26’s Disclosure Requirements.	18

CONCLUSION.....	19
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TABLE OF AUTHORITIES**Page(s)****Federal Cases**

<i>Brown v. Ill. Cent. R.R. Co.</i> , 705 F.3d 531 (5th Cir. 2013)	6, 11
<i>Brumley v. Pfizer, Inc.</i> , 200 F.R.D. 596 (S.D. Tex. 2001).....	12, 14
<i>Casey v. Ohio Medical Prods.</i> , 877 F. Supp. 1380 (N.D. Cal. 1995)	14
<i>City of Owensboro v. Ky. Utils. Co.</i> , No. 4:04CV-87-M, 2008 WL 4542674 (W.D. Ky. Oct. 8, 2008).....	19
<i>Coleman v. United States</i> , 912 F.3d 824 (5th Cir. 2019)	6
<i>Daubert v. Merrell Dow Pharms., Inc.</i> , 509 U.S. 579 (1993).....	6, 7, 8, 11
<i>In re Diet Drugs</i> , No. MDL 1203, 2001 WL 454586 (E.D. Pa. Feb. 1, 2001).....	14
<i>Ellis v. United States</i> , 673 F.3d 367 (5th Cir. 2012)	9
<i>Gen. Elec. Co. v. Joiner</i> , 522 U.S. 136 (1997).....	8, 13, 15
<i>Gortat v. Mylan, Inc.</i> , No. 3:09-cv-754-L, 2010 WL 11618710 (N.D. Tex. Nov. 15, 2010).....	8
<i>Guillory v. Domtar Indus., Inc.</i> , 95 F.3d 1320 (5th Cir. 1996)	12, 15, 16, 18
<i>Hathaway v. Bazany</i> , 507 F.3d 312 (5th Cir. 2007)	8
<i>Houston-Hines v. Hous. Indep. Sch. Dist.</i> , No. H-04-3539, 2006 WL 897209 (S.D. Tex. Apr. 4, 2006).....	8
<i>Knight v. Kirby Inland Marine Inc.</i> , 482 F.3d 347 (5th Cir. 2007)	7, 11
<i>Kumho Tire Co. v. Carmichael</i> , 526 U.S. 137 (1999).....	7, 13
<i>McClain v. Metabolife Int'l, Inc.</i> , 401 F.3d 1233 (11th Cir. 2005)	14

<i>McManaway v. KBR, Inc.</i> , 852 F.3d 444 (5th Cir. 2017)	12
<i>Moore v. Ashland Chem. Inc.</i> , 151 F.3d 269 276 (5th Cir. 1998)	7, 8, 13
<i>Paz v. Brush Engineered Materials, Inc.</i> , 555 F.3d 383 (5th Cir. 2009)	12, 16
<i>Pipitone v. Biomatrix, Inc.</i> , 288 F.3d 239 (5th Cir. 2002)	7
<i>Sims v. Kia Motors of Am., Inc.</i> , 839 F.3d 393 (5th Cir. 2016)	7
<i>Smelser v. Norfolk S. Ry. Co.</i> , 105 F.3d 299 (6th Cir. 1997), <i>abrogated on other grounds</i> , <i>Morales v. Am.</i> <i>Honda Motor Co.</i> , 151 F.3d 500 (6th Cir. 1998)	9
<i>Tanner v. Westbrook</i> , 174 F.3d 542 (5th Cir. 1999)	9
<i>Wagoner v. Schlumberger Tech. Corp.</i> , No. 07-CV-244-J, 2008 WL 5120750 (D. Wyo. June 19, 2008)	9, 10
<i>Wells v. SmithKline Beecham Corp.</i> , 601 F.3d 375 (5th Cir. 2010)	13
<i>Wilson v. Woods</i> , 163 F.3d 935 (5th Cir. 1999)	7, 8
State Cases	
<i>Combs v. Norfolk & W. Ry.</i> , 507 S.E.2d 355 (Va. 1998)	9
<i>People v. Dellinger</i> , 163 Cal. App. 3d 284 (1984)	9
Rules	
Fed. R. Civ. P. 26	18, 19
Fed. R. Civ. P. 26(a)(2)(B)	2
Fed. R. Evid. 702	1, 6, 7, 8, 19
Fed. R. Evid. 702(a)	7
Other Authorities	
AAP Policy Statement, <i>SIDS and Other Sleep-Related Infant Deaths: Expansion of Recommendations for a Safe Infant Sleeping Environment</i> (2011), at 1033- 1034	15

CDC, *Sudden Unexpected Infant Death and Sudden Infant Death Syndrome: Data and Statistics*, available at: <https://www.cdc.gov/sids/data.htm>1

Defendants Mattel, Inc. (“Mattel”) and Fisher-Price, Inc., (“Fisher-Price”) (collectively “Defendants”), by and through the undersigned counsel, and pursuant to Fed. R. Evid. 702, move to exclude or limit the opinions and testimony of Plaintiffs’ proposed expert, Erin Mannen, Ph.D. (“Mannen”). In support of this Motion, Defendants rely on the following Memorandum of Law.

INTRODUCTION

On December 14, 2015, A.K. (“Decedent”), a nearly five-month-old infant, was found unresponsive in a Fisher-Price Rock ‘n Play Sleeper (“RNPS”) by her daycare provider, former defendant Amy Morin (née Williams).¹ Decedent was found with her face pressed against a blanket that Mrs. Morin had used to cover the RNPS, contrary to the product’s warnings. After investigation and a full autopsy, the medical examiner concluded that Decedent’s cause of death was Sudden Infant Death Syndrome (“SIDS”).

Tragically, Decedent is one of the approximately 3,400 infants in the United States each year who, according to the CDC, pass away in their sleep in a “Sudden Unexpected Infant Death.” (See CDC, *Sudden Unexpected Infant Death and Sudden Infant Death Syndrome: Data and Statistics*, available at: <https://www.cdc.gov/sids/data.htm>). Plaintiffs, however, allege the RNPS was defective and caused Decedent’s death. To support their claims, Plaintiffs disclosed Mannen, a mechanical engineer, as an expert in the field of biomechanical engineering. The Court should exclude Mannen’s opinions for the following reasons.

First, Plaintiffs bear the burden of proving both general and specific causation; Mannen cannot carry this burden for them because she is not qualified to offer medical causation opinions. Despite admitting she is not a medical doctor and has no medical training or expertise, Mannen purports to offer a series of general and specific causation opinions premised on hypothetical scenarios in which she speculates that the design of the RNPS *might have* contributed to what she concludes was the “suffocation death” of the Decedent, counter to the medical examiner’s conclusion that Decedent’s cause of death was SIDS. Mannen is unqualified to reach these

¹ Defendants assume these facts are true for purposes of this Motion only.

conclusions because *none* of her biomechanical studies of infants in various sleep contexts over the past few years (the only studies on which she relies) was designed to assess whether the RNPS, or any inclined sleep product, can cause an infant to suffocate when that infant is placed supine (face up) and found supine “with her face in contact with the side of the product”—the position that Mannen believes applies to the Decedent in this case. (Dep. of Erin Mannen, Ph.D. (“Mannen Dep.”) at 65:7-8, Exh. 1).

Second, Mannen failed to employ a scientifically reliable methodology in reaching her improper causation opinions, rendering her opinions unreliable and irrelevant. Mannen relies on several wildly speculative hypotheses as to how the RNPS could potentially have contributed to the Decedent’s death. These hypotheses are impermissibly premised on speculation and conjecture, including because the studies on which Mannen relies expressly did not test these theories and Mannen did not conduct additional testing in connection with this litigation. Further, Mannen ignores critical record evidence that undercuts her opinions, including that Decedent’s face was obstructed by an added blanket when she was found in the RNPS. Mannen’s opinions also are refuted by the limited biomechanical measurements she purports to have performed in her own biomechanical studies. And because Mannen used an admittedly deformed RNPS of unknown origin for measurements that she relies on in forming her opinions in this case, any opinion based on those measurements is unreliable.

Last, Mannen failed to provide relevant underlying data that formed the basis of her opinions, as required by Fed. R. Civ. P. 26(a)(2)(B).

For all of these reasons, the Court should grant this Motion and exclude Mannen’s opinions.

FACTUAL BACKGROUND

I. The Rock ‘n Play Sleeper

The RNPS was an inclined sleep product designed for day use or overnight sleep, in which infants were placed supine (on their backs) at a less than 30-degree incline. (Joel Taft Feb. 11, 2022 Dep., at 565:11-566:10, Exh. 2). It featured a free-standing metal rocking frame, an attached

rigid plastic backing, a removable seat cushion and mattress pad with a fabric cover, and a three-point belt restraint system that, when properly engaged, secured a strap between the infant's legs and across the torso. (*Id.*; *see also* Joel Taft Feb. 10, 2022 Dep., at 243:17-244:24, Exh. 3). The inclined nature of the RNPS was observable to anyone looking at it. (*Id.* at 565:11-566:10). The product came with instructions for its assembly and safe use, as well as warnings, which were included in the instruction manual and also sewn onto the product itself. (Joel Taft Feb. 11, 2022 Dep., at 566:18-568:10, Exh. 2). As relevant to this motion, the warnings on the product included "ALWAYS use the pad provided, which includes the restraint, NEVER add a mattress, pillow, comforter, or padding[;]" and "SUFFOCATION HAZARD – Infants can suffocate . . . – on soft bedding." (AMK-CCPD-Photos-000412, Exh. 4). Defendants voluntarily recalled the RNPS on April 12, 2019.

II. The December 14, 2015 Incident

On December 14, 2015, Plaintiffs dropped the Decedent off at Mrs. Morin's daycare at approximately 8:30 a.m. (Jaclyn Kelley Dep., at 43:20-24, Exh. 5). At approximately 10 a.m., Mrs. Morin fed the Decedent and the Decedent fell asleep in Mrs. Morin's arms. (Amy Morin Dep., at 54:23-55:6, Exh. 6; *see also* Corpus Christi Police Department Records, at AMK-CCPD-Records-000013, Exh. 7). She then placed the Decedent in the subject RNPS, which she covered with a blue blanket that did not come with the RNPS, contrary to the RNPS warnings. (*Id.*)

Over two hours later, Mrs. Morin returned to check on the Decedent and found her unresponsive, on her side, and with her face pressed against the blanket covering the RNPS. (Jody Fedler Dep., at 54:1-16, Exh. 8; *see also* Corpus Christi Police Department Records, at AMK-CCPD-Records-000013, Exh. 7). Mrs. Morin immediately called 911 and first responders performed CPR on the Decedent while transporting her to the hospital. (*See* R000056, Exh. 9). The Decedent was noted to be deceased on arrival at the hospital and was transported to the medical examiner's office. (AMK-CSHCC-S-MD-000004-8, Exh. 10). The medical examiner concluded that the cause of the Decedent's death was SIDS. (Ray Fernandez, MD Dep., at 15:15-16:2, Exh. 11).

While investigating the scene of the incident, Sergeant Jody Fedler and Investigator Kenneth Muchek of the Corpus Christi Police Department took photographs, including photographs of the blanket that covered the RNPS at the time of the Decedent's death. (AMK-CCPD-Photos-000470-000483, Exh. 12). Sergeant Fedler interviewed Mrs. Morin at the police station, at which time she told him that she discovered the Decedent "on her side with her face pressed against the side of the bassinet." (See Jody Felder Supplemental Notes, at AMK-CCPD-Records-000029, Exh. 13). During his deposition, Sergeant Fedler testified that when he wrote this statement in his report, he meant that the Decedent's face was pressed against the *blanket* that was used to cover the RNPS, on the side of the product. (Jody Fedler Dep. at 54:8-16, Exh. 8).

III. Erin Mannen's Expert Report and Background

Mannen has a Ph.D. in mechanical engineering and self-identifies as a "world-renowned expert" in "infant biomechanics," but does not have any medical education, training or experience. (Mannen Dep. at 11:18-21, 20:13-14, 102:23-24, Exh. 1). At her deposition, Mannen admitted, "I'm not a medical expert . . . I can't give you a medical opinion" and "I'm not a causation expert." (*Id.* at 52:17, 84:21, 84:25-85:2, 85:22, 102:23-24). Nevertheless, Mannen's Report offers a series of opinions on general and specific medical causation. (Mannen Expert Report ("Report") at 3, 10-11, 20-24, 26-27, Exh. 14). Plaintiff's counsel asked Mannen "to determine if and how the design of [the Decedent's] sleep product influenced biomechanics (movement and body position) of [the Decedent]" on the assumption that the Decedent died of "suffocation" (*id.* at 3), despite the undisputed fact that the Decedent's cause of death was SIDS. (Ray Fernandez, MD Dep., at 15:15-16:2, Exh. 11). According to Mannen, the "design" of the RNPS might have "resulted in a dangerous biomechanical position that contributed to the suffocation death of [the Decedent]." (Report at 3, Exh. 14).

Mannen's Report fails to identify any cognizable methodology that she employed in arriving at any general or specific medical causation opinions. In her "Methodology" section—just two paragraphs of her Report—Mannen states merely that the "methods used in my analysis" are "the same methods" used in her non-peer reviewed 2019 Consumer Product Safety

Commission study (the “2019 Study”) and two related articles, which include, among other things, (i) “product measurements” and (ii) “common experimental techniques (motion capture, electromyography, and oxygen saturation)” for “data collection.” (Report at 12, Exh. 14).

While Mannen says that the RNPS at issue here “is functionally equivalent and substantially similar” to “product S01 in the 2019 [] Study,” and thus, the “data” from “product S01” in that study “can be reliably used” in this case (*id.* ¶ 2), Mannen refused to provide all underlying data from that study to Defendants. In her 2019 Study, Mannen collected kinematic and EMG data from 10 infants, measured for between 30-60 seconds, and then compared that data from inclined sleep products to the data from the custom-built inclined crib mattress at 0°. (2019 CPSC Report, at 26-27, Exh. 15). Notably, for product S01, Mannen found *no statistically significant* differences for supine infants in the RNPS as compared to a crib at 0° in terms of neck range of motion (“ROM”), neck peaks, trunk peaks, erector spinae, paraspinals, or abdominal muscular activity, and found a decrease in trunk ROM. (*Id.* at 40-41, 49-50).

Mannen offers several wildly speculative hypotheses as to how the RNPS could potentially have contributed to the Decedent’s death:

- **“Chin-to-Chest” Positional Asphyxiation After Extreme “Neck Flexion” During Sleep:** Mannen hypothesizes that at some point during her sleep, the Decedent might have gotten into an extreme “chin-to-chest” position due to some *unknown and unspecified cause* and then remained in that gravity-defying position long enough that an extreme “neck flexion” might have caused her to die of positional asphyxiation, before the Decedent returned back to the same position she had been placed.
- **Carbon-Dioxide “Rebreathing” After 90-Degree Head Turn During Sleep:** Mannen also hypothesizes that, based on her measurements of the admittedly deformed RNPS that she used as an exemplar in this case, *if* the Decedent’s head was turned “90 degrees” from the supine position, her nose and mouth might have come in contact with the sides of the RNPS, which Mannen then says might have presented a “dangerous CO2 rebreathing and/or suffocation scenario” if the Decedent remained in that position

long enough to stop breathing. Mannen failed to consider the effect of the presence of the blanket that was covering the RNPS as part of her hypotheses.

- ***Death By Decreased Oxygenation During Sleep***: Mannen further hypothesizes that, while lying supine in the RNPS, the Decedent might have experienced a radical decrease in oxygenation resulting in her death, *if* the Decedent was in a “flexed trunk” position, which Mannen says “inhibits normal breathing based on medical literature”—even though Mannen is admittedly not a medical expert and her own biomechanical testing of infants supine in the RNPS found *no decrease in oxygenation levels*.

None of Mannen’s hypotheses is supported by the actual evidence in the record nor the studies on which she purports to rely. At her deposition, Mannen could not point to *any actual facts* about the Decedent at the time of the incident that support any of her speculative causation theories. For example, Mannen admitted she had no basis to testify that, at the time of the incident, the Decedent was in the sort of “flexed trunk” position hypothesized, because such information was not indicated in the Decedent’s records nor had Mannen reviewed the deposition transcripts of the detective and medical examiner who had investigated the incident before she wrote her Report on July 11, 2022. (Mannen Dep. at 66:24-67:25, Exh. 1).

LEGAL STANDARD

Federal Rule of Evidence 702 controls the admission of expert testimony. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 587 (1993).² Under Rule 702, the Court must serve as a gatekeeper to the admission of scientific testimony. *See id.* at 589; *Brown v. Ill. Cent. R.R. Co.*, 705 F.3d 531, 535 (5th Cir. 2013) (emphasizing the role of the trial court as a “gatekeeper”). This requires the Court to conduct “a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.” *Daubert*, 509 U.S. at 592-93. This gatekeeping

² In a federal court sitting in diversity jurisdiction, the admissibility of expert testimony is a question of and controlled by federal law. *Coleman v. United States*, 912 F.3d 824, 831 (5th Cir. 2019).

function applies not only to “scientific” testimony, but also to testimony based on “technical” and “other specialized” knowledge. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999).

As such, an expert witness must satisfy three prerequisites before their opinion is admissible: (1) they must be qualified to testify on that subject matter; (2) their testimony must be relevant; and (3) their testimony must be reliable. *See Daubert*, 509 U.S. at 589-90; *Wilson v. Woods*, 163 F.3d 935, 937 (5th Cir. 1999); *Moore v. Ashland Chem. Inc.*, 151 F.3d 269 276 (5th Cir. 1998); *Knight v. Kirby Inland Marine Inc.*, 482 F.3d 347, 352-355 (5th Cir. 2007). The proponent of the expert testimony bears the burden of establishing that each of these criteria is satisfied. *See Sims v. Kia Motors of Am., Inc.*, 839 F.3d 393, 400 (5th Cir. 2016).

First, for an expert witness to be adequately qualified by virtue of his or her specialized “knowledge, skill, experience, training, or education,” Fed. R. Evid. 702, the expert’s qualifications must be sufficiently related to the particular subjects at issue in the case. *Wilson*, 163 F.3d at 937 (“district court should refuse to allow an expert witness to testify if it finds that the witness is not qualified to testify in a particular field or on a given subject”).

Second, for an expert’s opinion to be relevant, it must assist “the trier of fact to understand the evidence or to determine a fact in issue.” *See* Fed. R. Evid. 702(a). “Relevance depends upon ‘whether [the] reasoning or methodology properly can be applied to the facts in issue.’” *Knight*, 482 F.3d at 352. An equivocal or ambiguous opinion is not relevant because it “does not make any fact more or less probable.” *Accord Pipitone v. Biomatrix, Inc.*, 288 F.3d 239, 245 (5th Cir. 2002) (excluding an expert’s causation testimony as “not helpful to the fact-finder because of his inability to conclude that it was more likely than not that the [defendant’s product] caused the infection....”).

Third, for an expert’s scientific or technical opinion to be reliable, the expert must “employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Kumho Tire Co.*, 526 U.S. at 152. “[T]he expert’s testimony must be reliable at each and every step or else it is inadmissible. ‘The reliability analysis applies to all aspects of an expert’s testimony; the methodology, the facts underlying the expert’s opinion, the link between the facts and the conclusion, et alia.’” *Knight*, 482 F.3d at 355. Whether the “theory

or technique has been subjected to peer review and publication” is one factor for the court to consider “in assessing the scientific validity of a particular technique or methodology on which an opinion is premised.” *Daubert*, 509 U.S. at 594. Moreover, “trial courts are encouraged to exclude . . . speculative testimony as lacking any scientific validity.” *Moore*, 151 F.3d at 279.

Where the proponent of the expert testimony fails to establish these prerequisites, exclusion of expert testimony is within the court’s sound discretion. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 142 (1997).

ARGUMENT

I. Mannen Admits She Is Not Qualified to Testify on Any Medical Issues, Including Medical Causation, And Should Be Precluded from Offering Any Testimony and Opinions She Has Disclaimed.

Plaintiffs cannot sustain their burden to prove that Mannen is qualified under Rule 702 to offer any medical opinions, including opinions on what actually caused or could have caused the Decedent’s death. Mannen has a Ph.D. in mechanical engineering (not “biomechanical engineering” or “biomedical engineering”), is “not a medical doctor,” and has no medical education, training, or experience. (Mannen Dep. at 20:13-14, 102:23-24, Exh. 1). Nor is Mannen qualified to offer general or specific medical causation opinions.

An expert must be qualified on the particular subject upon which he or she is giving expert testimony. *Wilson*, 163 F.3d at 937 (“district court should refuse to allow an expert witness to testify if it finds that the witness is not qualified to testify in a particular field or on a given subject”). An expert is only permitted to offer testimony within the bounds of their qualifications and may not offer opinions outside their area of expertise. *E.g.*, *Hathaway v. Bazany*, 507 F.3d 312, 317 (5th Cir. 2007); *see also Gortat v. Mylan, Inc.*, No. 3:09-cv-754-L, 2010 WL 11618710, at *8 (N.D. Tex. Nov. 15, 2010) (rejecting argument that physician’s experience in practice sufficiently qualified him to render opinion on adequacy of warnings/label; precluding testimony based on adverse event reports that risks should have been included in warnings); *Houston-Hines v. Hous. Indep. Sch. Dist.*, No. H-04-3539, 2006 WL 897209, at *3 (S.D. Tex. Apr. 4, 2006) (finding a 29-year veteran police officer unqualified as an expert witness due to his lack of

experience in the type of policing relevant to the issue at trial). Medical causation can only be determined by expert medical testimony. *Ellis v. United States*, 673 F.3d 367, 373 (5th Cir. 2012) (“Expert testimony is necessary to establish causation as to medical conditions outside the common knowledge and experience of [the finder of fact].”).

As a mechanical engineer with no medical background, Mannen simply does not have the relevant expertise to offer competent testimony on causation in this case—either general causation or specific causation. *See Tanner v. Westbrook*, 174 F.3d 542 (5th Cir. 1999) (finding the specificity of the issue requires a tight fit between an expert’s background and the content of their testimony); *see also Smelser v. Norfolk S. Ry. Co.*, 105 F.3d 299, 305 (6th Cir. 1997) (“Huston’s opinion testimony about causation also should have been excluded” as “it goes beyond his expertise in biomechanics”), *abrogated on other grounds, Morales v. Am. Honda Motor Co.*, 151 F.3d 500, 515 (6th Cir. 1998); *Combs v. Norfolk & W. Ry.*, 507 S.E.2d 355, 358-59 (Va. 1998) (“an expert in the field of biomechanical engineering” who is “not a medical doctor” is “not qualified to state an expert medical opinion”); *Wagoner v. Schlumberger Tech. Corp.*, No. 07-CV-244-J, 2008 WL 5120750, *1 (D. Wyo. June 19, 2008) (“Biomechanics” experts are not “qualified to provide medical opinions”); *People v. Dellinger*, 163 Cal. App. 3d 284, 293-95 (1984) (affirming exclusion of causation testimony from expert with a “Ph.D. in biomechanical engineering” who had “no medical background or experience” and “her application of general principles of biomechanics to this specific situation involving a child’s fall is insufficient for admissibility”; “In considering whether a person qualifies as an expert, the field of expertise must be carefully distinguished and limited.”) (citation omitted).

Despite her admitted lack of qualifications in the medical field, Mannen unabashedly attempts to offer medical causation opinions—including as to the specific cause of the Decedent’s death—based on her unqualified medical assessments and speculative *ipse dixit*. For example, she opines that the design of the RNPS (i) “resulted in a dangerous biomechanical position that contributed to the suffocation death of [the Decedent],” and “can cause suffocation, like in the case of [the Decedent]” (Report at 3, 27 ¶ 11, Exh. 14); (ii) “results in a flexed trunk posture during

supine lying, a position that *inhibits normal breathing*,” based on Mannen’s claimed review of “medical literature” (*id.* at 3, 26 ¶ 3 (emphasis added)); (iii) “makes it easier for babies to obtain the *dangerous chin-to-chest position*,” which “could have led to *positional asphyxia*” (*id.* at 10, 26 ¶ 6 (emphases added)); (iv) “puts infants at *higher demand to maintain pulmonary function*, leading to an increased risk for *suffocation*” (*id.* at 11 (emphases added)); (v) “*compromised* [the Decedent]’s *respiration* and could have led to positional asphyxia” (*id.* at 26 ¶ 6 (emphases added)); and (vi) “*results in a dangerous CO2 rebreathing and/or suffocation scenario*,” “if [the Decedent]’s head was turned 90-degrees” and “her nose and mouth” were fully obstructed by the sides of the RNPS (*id.* at 22, 26 ¶ 5 (emphases added)). These are all indisputably medical causation opinions that Mannen is not qualified to render, and the Court should exclude them.

In addition to excluding Mannen from offering any testimony and opinions concerning medical causation, Mannen should also be precluded from offering any opinions that she has disclaimed. Specifically, Mannen admits she has no expertise in designing infant products (Mannen Dep. at 33:7, Exh. 1), infant product labels or warnings (*id.* at 52:11-12), and foreseeable misuse (*id.* at 144:8-145:15). Accordingly, Mannen should not be permitted to testify on any of these subjects at trial.

II. Mannen’s Testimony and Opinions Are Neither Reliable nor Relevant and Should Be Excluded.

A. Mannen Did Not Employ Any Scientifically Reliable Methodology in Reaching Her Opinions.

Mannen seeks to offer a general causation opinion—that the design of the RNPS can cause an infant to suffocate—based on several speculative and untested litigation-driven hypotheses. Mannen describes her “[m]ethodology” in reaching this opinion as merely involving “data collection,” including the taking of “product measurements,” plus the “methods” used in her 2019 Study, i.e., “motion capture, electromyography, and oxygen saturation.” (Report at 12, Ex. 14). But *none* of Mannen’s biomechanical studies, including her non-peer reviewed 2019 Study, was designed to test and determine whether inclined sleep products can cause a supine infant to suffocate, including in any of the ways Mannen hypothesizes in her Report. (*See* pp. 13-14, *infra*).

Thus, *none* of the studies on which Mannen relies provide a scientifically valid, reliable, or generally accepted methodology to determine general or specific causation in this case. *See Knight*, 482 F.3d at 352-355 (“Of the over fifty studies relied upon by Dr. Levy, none gave an adequate basis for the opinion that the types of chemicals appellants were exposed to can cause their particular injuries in the general population.”); *Brown*, 705 F.3d at 535 (explaining trial court’s “gatekeeping role” ensures expert’s principles and methodology are scientifically reliable). Nor did Mannen engage in any testing of her hypotheses in connection with this litigation. (Mannen Dep., at 189:18-22; 197:17-198:3; 206:6-11, Exh. 1).

Instead, Mannen merely expresses her own views and beliefs about how her prior studies purport to show that an infant who is placed supine in the RNPS and found supine (as Mannen believes to be the case here) can suffocate in the RNPS because of its design—even though none of her studies reached, or even investigated, this conclusion. It is fundamental that expert testimony must be “derived from the scientific method” and “the methods and procedures of science,” not “subjective belief or unfounded speculation.” *Daubert*, 509 U.S. at 590 (“‘scientific methodology’” is “‘based on generating hypotheses and testing them to see if they can be falsified’”) (citation omitted). Further, as discussed in detail below, Mannen ignored any contrary evidence in the record that could call into doubt her conclusions. Mannen’s opinions here are “not based on ‘good grounds’” because “the data relied on by [her] fail[s] to provide a ‘relevant’ link with the facts at issue.” *Knight*, 482 F.3d at 355. Her opinions are therefore unreliable and irrelevant and should be excluded.

B. Mannen’s Speculative Hypotheses and Opinions Are Based on Factual Assumptions Without Evidentiary Support, And There Is Too Great an Analytical Gap Between Her Study Data and Her Litigation Opinions.

Mannen’s causation opinions rest on three hypothetical scenarios that she speculates might have happened during the Decedent’s sleep, but that are not supported by the evidence and, in fact, are contradicted by the testimony of the Decedent’s caregiver and the investigating officer, the medical examiner’s report, and the opinions of another of Plaintiffs’ experts. Expert opinions based on hypothetical possibilities premised on false assumptions are not reliable and should be

excluded. *See, e.g., Guillory v. Domtar Indus., Inc.*, 95 F.3d 1320, 1331 (5th Cir. 1996) (if “expert’s testimony is ‘not based upon the facts in the record but on altered facts and speculation designed to bolster [a party’s] position,’ the trial court should exclude it”); *McManaway v. KBR, Inc.*, 852 F.3d 444, 449 (5th Cir. 2017) (excluding *ipse dixit* testimony); *Paz v. Brush Engineered Materials, Inc.*, 555 F.3d 383, 389 (5th Cir. 2009) (affirming the exclusion of an expert opinion that relied on false assumptions rebutted by undisputed evidence in the record); *Brumley v. Pfizer, Inc.*, 200 F.R.D. 596, 601 (S.D. Tex. 2001) (“[T]he trial court may exclude evidence when based on inaccurate or purely hypothetical premises.”).

1. Mannen’s Testimony Based on Her Speculative “Chin-To-Chest” Hypothesis Must Be Excluded.

There is no factual basis for Mannen’s speculative hypothesis that, at some point during her sleep, the Decedent may somehow have gotten into a “dangerous chin-to-chest position” that “could have led to positional asphyxia.” (*See* Report at 10, 26 ¶ 6, Exh. 14). Mannen speculates that the RNPS’s incline might have made that hypothetical scenario “easier” to the extent it caused the Decedent to be in a “flexed trunk” position. *Id.* But at her deposition, Mannen admitted she had *no factual basis* to testify that the Decedent was ever in either a “flexed trunk” position or any “dangerous chin-to-chest position” at the time of the incident. (*See* Mannen Dep. at 196:12-197:2, Exh. 1). Nor could she, as the record evidence does not support such a theory.

Instead, the record evidence shows that the Decedent’s official cause of death was SIDS. (Ray Fernandez, MD Dep., at 15:15-16:2, Exh. 11). Mannen’s “chin-to-chest” hypothesis ignores this evidence. The record evidence also shows that the Decedent was found on her side, and not on her back as Mannen posits. (*See* Jody Felder Supplemental Notes, at AMK-CCPD-Records-000029, Exh. 13; Jody Fedler Dep. at 54:8-16, Exh. 8). Mannen’s “chin-to-chest” hypothesis also ignores this evidence. Indeed, Mannen fails to reconcile her theory of causation with another of Plaintiffs’ experts, Dr. Eisenstat, who opines that the Decedent allegedly suffocated while on her side and not on her back as Mannen posits.

The basis for Mannen’s “chin-to-chest” hypothesis is nothing but pure speculation, which is precisely why the Court should exclude it. In fact, in her own most-recent publication, Mannen wrote that she and her co-authors could only “*speculate* that this flexed-trunk body position which renders additional trunk movement difficult, *might* explain the incidence of infants found in a chin-to-chest position as noted in some incident reports (Consumer Product Safety Commission, 2019).” (Wang 2021 at 6 (emphases added), Exh. 17). Despite this concession outside of litigation that her theory is mere speculation, Mannen now purports to offer a medical causation opinion premised on that same admittedly speculative chin-to-chest theory, without any new study or new data. This is a classic instance in which an expert must be excluded for having failed to “employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Kumho Tire Co.*, 526 U.S. at 152; *see also Moore*, 151 F.3d at 278 (affirming underlying finding that an expert’s reliance on an article where the authors “made it clear their conclusions were speculative because of the limitations of the study” was unreliable under *Daubert*).

There is simply “too great an analytical gap,” *Joiner*, 522 U.S. at 146, between Mannen’s *ipse dixit* assertion in her Report that the RNPS’s design “makes it easier” for an infant to “obtain” a “dangerous” chin-to-chest position and Mannen’s biomechanical studies, which reached no such conclusion. (Report at 10, 26, Exh. 14). Mannen not only admits that she did not observe any “chin-to-chest” incidents in any of her testing of infants in inclined sleepers, but also that none of her research “studied” the chin-to-chest position or scenario. (*See, e.g.*, Mannen Dep. at 206:6-11 (“Q. . . . did you study the force needed to achieve this chin-to-chest position that you’re talking about in any of the studies, CPSC or Wang ‘20, ‘21? A. That wasn’t an outcome of -- of any of the studies, no.”), Exh. 1); *see also* 2019 CPSC Report at 6 (“the impact of the chin-to-chest position in inclined sleep products is unknown”), Exh. 15).³

³ Although Mannen has previously alluded to anecdotal incident reports to the CPSC about infants being found in a chin-to-chest position, such unconfirmed incident reports are not evidence upon which an expert may reasonably rely for a causation opinion. Courts across the country have repeatedly excluded expert opinion testimony based on comparable adverse event reporting or incident reports because they are not reliable scientific evidence of causation. *See, e.g., Wells v. SmithKline Beecham Corp.*, 601 F.3d 375, 380–81 (5th Cir. 2010) (finding testimony based on

If anything, Mannen’s data from her biomechanical studies of infants in the RNPS refutes Mannen’s chin-to-chest theory in this case rather than supports it. For product S01—which according to Mannen was in fact an RNPS—her 2019 Study reported *no statistically significant* differences for supine infants in the RNPS as compared to a crib at 0° in terms of neck ROM, neck peaks, trunk peaks, erector spinae, paraspinals, or abdominal muscular activity, and found a decrease in trunk ROM. (2019 CPSC Report at 40-41, 49-50, Exh. 15). And Mannen’s later publication reports that for “[s]upine positioning” in inclined sleep products (like the Decedent who was initially placed supine in this case), “[i]nfants *moved less*” and “also showed *no differences in the number of times they lifted their heads* in the inclined products,” “*no changes in the neck and trunk muscle activity,*” and “*no changes in neck or trunk ROMs.*” (Wang 2021 at 5-6 (emphasis added), Exh. 17). These results do not support Mannen’s speculative hypothesis that that Decedent died from attaining a “dangerous chin-to-chest position.” See *Brumley*, 200 F.R.D. at 602 (“Plaintiffs cannot use the Phillips study to support a conclusion that the study itself does not make.”).

Simply put, Mannen’s “chin-to-chest” hypothesis is speculative, unsupported by the record evidence, and void of any scientific support. The Court should exclude it.

2. Mannen’s Testimony Based On Her Speculative 90°-Head Turn/“Carbon-Dioxide Rebreathing” Theory Must Be Excluded.

Mannen also has no factual basis or evidentiary support for her wildly speculative theory that the Decedent might have died from “a dangerous CO2 rebreathing and/or suffocation scenario” related to the design of the RNPS “if [the Decedent’s] head was turned 90-degrees” such that her “nose and mouth” were fully obstructed by the sides of the RNPS. (Report at 21-23, 26 ¶ 5, Exh. 14). This theory ignores entirely the record evidence that shows the RNPS was covered by a blanket, including the investigating officer’s testimony that the Decedent’s face was covered by

“anecdotal evidence” did not meet threshold for admission of expert testimony under *Daubert* standard); *McClain v. Metabolife Int’l, Inc.*, 401 F.3d 1233, 1250 (11th Cir. 2005) (“anecdotal reports” about adverse events are “one of the least reliable sources to justify opinions about both general and individual causation”); *Casey v. Ohio Medical Prods.*, 877 F. Supp. 1380, 1385 (N.D. Cal. 1995) (same); see also *In re Diet Drugs*, No. MDL 1203, 2001 WL 454586, *15 (E.D. Pa. Feb. 1, 2001) (incident reports, which contain anecdotal information based on exposure to a product and alleged injury, are “universally recognized as insufficient and unreliable evidence of causation”).

the blanket (Jody Fedler Dep. at 54:8-16, Exh. 8). Thus, the Decedent's nose and mouth could not have been obstructed by the sides of the RNPS, but rather only by the blanket that was placed in the RNPS contrary to the warnings and instructions.⁴

Mannen's failure to address the blanket ends the inquiry on this hypothetical. But even if it did not, Mannen still does not identify any scientific basis for her rebreathing theory, and none of her own research studies support it. (*See* Wang 2021 at 7 ("this study did not take into consideration CO₂ rebreathing and sleep surface breathability"), Exh. 17; 2019 CPSC Report at 7 ("no breathability analysis was conducted as part of this study," so it is unknown whether "the material or design of the product promoted carbon dioxide rebreathing or suffocation"), Exh. 15). Consequently, Mannen's speculative opinion on this issue is completely unconnected to any of her own existing data and research and a textbook example of "*ipse dixit*." *Joiner*, 522 U.S. at 146; *Guillory*, 95 F.3d at 1331 (affirming district court's exclusion of expert testimony based on facts not in the record and speculation designed to bolster proponent's position).

Moreover, Mannen did nothing "new" to test her speculative hypothesis in litigation, nor did she even try to perform any biomechanical or other hypothesis testing to assess whether (i) a sleeping infant could in fact turn her head 90 degrees unassisted; (ii) such a hypothetical 90-degree head turn could result in the complete obstruction of the infant's nose and mouth such that Mannen's CO₂ rebreathing hypothesis is even possible; and even if so (iii) the sleeping infant could hold her head in that position long enough, unassisted, such that the infant actually could expire from rebreathing her own exhaled CO₂. Mannen has conducted no CO₂ rebreathing testing whatsoever in connection with any inclined sleep product, including the RNPS. Because Mannen's Report does not recite any of the many "foundational" essentials that would be required before her new-found CO₂ rebreathing hypothesis could be presented to a jury, Mannen's causation testimony

⁴ The American Academy of Pediatrics ("AAP") specifically recommends keeping the baby's sleep space free of blankets to reduce the risk of SIDS/SUID. *See* AAP Policy Statement, *SIDS and Other Sleep-Related Infant Deaths: Expansion of Recommendations for a Safe Infant Sleeping Environment* (2011), at 1033-1034 ("Keep soft objects and loose bedding out of the crib to reduce the risk of SIDS, suffocation, entrapment, and strangulation. . . . b. Loose bedding, such as blankets and sheets, might be hazardous and should not be used in the infant's sleeping environment."), Exh. 18).

premised on this impermissibly speculative and factually unsupported hypothesis must be excluded under *Daubert*. *See Paz*, 555 F.3d at 389 (affirming the exclusion of an expert opinion that relied on false assumptions rebutted by undisputed evidence in the record).

3. Mannen’s Testimony Based on Her Speculative “Decreased Oxygenation” Hypothesis Must Be Excluded.

Mannen also has no factual basis for her final hypothesis, which is based on her speculation that the Decedent might have died from a decrease in oxygenation because, as Mannen posits, the RNPS’s design promotes infants being in a “flexed trunk” position when lying supine, which Mannen says “inhibits normal breathing based on medical literature.” (Report at 26 ¶ 3, Exh. 14). This theory is also impermissibly based on factual assumptions without evidentiary support, as well as speculation and conjecture.

As noted, Mannen has no evidentiary basis upon which to testify that the Decedent was in fact in any “flexed trunk” position at the time of the incident on December 14, 2015. (*See Mannen Dep.* at 196:12-197:2, Exh. 1). Without the requisite factual basis that the Decedent actually was in a “flexed trunk” position at the time of the incident, Mannen’s opinion that the design of the RNPS “promotes a flexed trunk position” that might inhibit normal breathing (Report at 26 ¶ 6, Exh. 14), must be excluded as speculative or irrelevant expert opinion. *Guillory*, 95 F.3d at 1331 (if “expert’s testimony is ‘not based upon the facts in the record but on altered facts and speculation designed to bolster [a party’s] position,’ the trial court should exclude it”).

Moreover, Mannen’s decreased-oxygenation hypothesis is contradicted by her own data from her non-peer reviewed 2019 Study. As Mannen admits, her 2019 Study used a medical grade pulse oximeter to measure the infant subjects’ oxygen saturation levels when they were placed supine in each of the seven products tested in that study, (2019 CPSC Report at 27-28, Exh. 15), including “product S01,” the data from which Mannen says “can reliably be used” in this case. (*See Report* 26 ¶ 2, Exh. 14). The reported oxygenation results demonstrated that “[n]o babies experienced problems in any supine lying position.” (2019 CPSC Report at 54, Exh. 15). These reported results from Mannen’s own research contradict her speculative hypothesis that sleeping

supine in the RNPS, at its less than 30-degree incline, somehow caused the Decedent to suffocate due to a lack of oxygen if, in fact, she was in a flexed trunk position.⁵

In sum, Mannen is left with nothing but speculation upon unfounded speculation for her *ipse dixit* assertion that the Decedent might have died of “suffocation” resulting from some radical decrease in oxygenation related to the design of the RNPS. Mannen has no competent, non-speculative basis to offer any reliable expert opinion on the issues of general or specific medical causation; her unqualified, unscientific, and speculative opinions must be excluded under *Daubert*.

4. Mannen’s Testimony Based on A Mysterious RNPS that She Received Second-Hand from an Unknown Source Must Be Excluded.

Mannen additionally opines that “[t]he plastic surface [of the RNPS insert] apparently experienced deformation which made the product even more unsafe than the original design.” (Report at 26 ¶7, Exh. 14; *see also* Mannen Dep. at 219:11-15, Exh. 1). However, Mannen admits that her opinion is based entirely on a used RNPS—which is not the subject RNPS, nor did she know whether it is even the same model at issue in this case—that she mysteriously received from an unknown source. (Mannen Dep. at 220:7-221:7, 221:13-21, Exh. 1). Mannen confirmed that her exemplar RNPS was deformed at the time she received it, so she has no first-hand knowledge regarding how the product came to be in the condition it was upon her obtaining it. (Report at 26 (“The plastic surface apparently experienced deformation”), Exh. 14; *see also id.* at 23). Mannen also admitted that she based all of the measurements that she relies on here on this deformed RNPS. (Mannen Dep. at 221:2-7, Exh. 1; Report at 14 (“I examined the exemplar product alone.”), Exh. 14).

While the subject RNPS was unavailable to any party after being disposed of by local law enforcement, Mannen admitted at her deposition that she never attempted to obtain another exemplar from Defendants or any other verifiable source. (Mannen Dep. at 222:18-23, Exh. 1). All of Mannen’s opinions premised on the deformed RNPS should be excluded as unreliable,

⁵ Mannen tries to disregard the oxygenation testing from her own studies by positing that “medical literature” suggests that a flexed trunk position “inhibits normal breathing” (Report at 26 ¶ 3, Exh. 14), but as discussed herein, Mannen is admittedly unqualified to offer any medical opinions. (*See* pp. 8-10, *supra*).

because (1) the mystery RNPS was deformed when she received it, (2) it is unknown how and for what purpose the mystery RNPS was previously used, (3) there is no way of knowing whether the mystery RNPS was altered by its prior owner or not functioning as intended, (4) Mannen never sought to obtain a new RNPS for comparison, and (5). Mannen does not claim that the subject RNPS in this case had the same deformity as the one she reviewed.

Even if one were to set aside the detective’s testimony making clear that the Decedent’s face was covered by the blanket and was not pressed into the side of the RNPS (Jody Fedler Dep. at 54:8-16, Exh. 8)—which Mannen ignored—her decision to rely entirely on a deformed, second-hand product to speculate as to the placement of the Decedent’s face makes no sense. The fact that she used a deformed product could have a material impact on her measurements, rendering them wholly unreliable. Mannen does not account for this; indeed, her report is silent on the issue. “If the foundational data underlying opinion testimony are unreliable, an expert will not be permitted to base an opinion on that data because any opinion drawn from that data is unreliable.” *See Guillory*, 95 F.3d at 1331. Accordingly, all of Mannen’s opinions based on the mystery RNPS should be excluded.

III. Mannen’s Failure to Provide the Underlying Data Upon Which Her Opinions Are Based Violates Rule 26’s Disclosure Requirements.

Mannen purports to base her opinions on her three inter-related “biomechanical” studies: her unpublished, non-peer reviewed 2019 CPSC Report and the two articles she co-authored, Wang 2020 and Wang 2021. Even though Mannen claims that data for “product S01” in her 2019 Study “can be reliably used” in this case, she refused to produce the underlying data from her studies, claiming she does not have the data and that it is “confidential.” (Mannen Dep. at 131:17-21, 161:5-9, Exh. 1). Mannen also refused to answer any questions about discussions with the CPSC related to her 2019 Study on “confidentiality” grounds. (*Id.*)

Plaintiffs’ failure to provide Defendants with the underlying data from the studies on which Mannen purports to rely for her opinions in this case violates Rule 26’s disclosure requirements. This alone is a sufficient basis to exclude Mannen’s opinions, even before considering their other

shortcomings. *See, e.g., City of Owensboro v. Ky. Utils. Co.*, No. 4:04CV-87-M, 2008 WL 4542674, *2-3 (W.D. Ky. Oct. 8, 2008) (granting motion to exclude expert from testifying, where the expert based his opinion on “confidential” documents that were never produced in unredacted form to the opposing party, because the failure to produce the documents in unredacted form “deprived [the opposing party] of the opportunity to determine whether the unidentified plants are comparable” or “to test the accuracy and validity of [the expert’s] similar plant data”). Excluding Mannen’s opinion on this basis is consistent with this Court’s acknowledgment during the August 5, 2022 pre-motion conference that Mannen’s failure to produce her underlying data may expose her to exclusion under *Daubert* and Rule 702. (Hr’g Tr. (Aug. 5, 2022), at 14:2-4, Exh 16). The Court should therefore exclude Mannen’s opinions for failure to comply with Rule 26’s disclosure requirements.

CONCLUSION

For the foregoing reasons, Mannen should be excluded from testifying at trial as an expert in this case.

Dated: February 13, 2023

Respectfully Submitted,

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***Attorneys for Defendants Mattel, Inc. and
Fisher-Price, Inc.***

CERTIFICATE OF CONFERENCE

I hereby certified the undersigned, counsel for Defendants, conferred with Plaintiffs' counsel regarding Defendants' Motion to Exclude or Limit Opinions and Testimony of Erin Mannen, Ph.D. and Incorporated Memorandum of Law. Plaintiffs' counsel stated it opposes Defendants' Motion.

/s/ Mary-Olga Lovett

Mary-Olga Lovett

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing document has been filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all counsel of record on this 13th day of February 2023.

/s/ Mary-Olga Lovett

Mary-Olga Lovett

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
CORPUS CHRISTI DIVISION**

JACLYN KELLEY, Individually, and JOSHUA
KELLEY, Individually, and as Personal
Representatives of the Estate of A. K.,

Plaintiffs,

v.

FISHER-PRICE, INC.; MATTEL, INC.; AMY
RENEE WILLIAMS a/k/a AMY MORIN,

Defendants.

Case No. 2:21-CV-231

**DECLARATION OF MARY-OLGA LOVETT IN SUPPORT OF DEFENDANTS’
MOTION TO EXCLUDE OR LIMIT THE OPINIONS AND TESTIMONY OF ERIN
MANNEN, PH.D. AND INCORPORATED MEMORANDUM OF LAW**

I, Mary-Olga Lovett, hereby declare as follows:

1. I am an attorney duly admitted to practice law in the State of Texas and in the Southern District of Texas. I am a Shareholder with the law firm Greenberg Traurig, LLP, and counsel of record for Defendants Mattel, Inc. and Fisher-Price, Inc. (collectively, “Defendants”) in the above-captioned action. I make this Declaration in support of Defendants’ Motion to Exclude or Limit Opinions and Testimony of Erin Mannen, Ph.D. and Incorporated Memorandum of Law in Support.

2. I have personal knowledge of the facts set forth in this declaration and, if called as a witness, could and would competently testify thereto.

3. Attached hereto as **Exhibit 1** is a copy of the deposition transcript of Erin M. Mannen, Ph.D., dated October 23, 2022, taken in the above-captioned case.

4. Attached hereto as **Exhibit 2** is a copy of the relevant excerpts of the deposition transcript of Joel Taft, dated February 11, 2022, taken in *Padovani, et al. v. Fisher-Price, Inc., et al.* (Case No. 19STCV42307), filed in the Los Angeles Superior Court of California.

5. Attached hereto as **Exhibit 3** is a copy of the relevant excerpts of the deposition transcript of Joel Taft, dated February 10, 2022, taken in *Padovani, et al. v. Fisher-Price, Inc., et al.* (Case No. 19STCV42307), filed in the Los Angeles Superior Court of California.

6. Attached hereto as **Exhibit 4** is a copy of documents produced in the above-captioned case with Bates No. AMK-CCPD-Photos-000412.

7. Attached hereto as **Exhibit 5** is a copy of the deposition transcript of Jaclyn Kelly, dated August 5, 2021, taken in the above-captioned case.

8. Attached hereto as **Exhibit 6** is a copy of the deposition transcript of Amy Williams Morin, dated August 31, 2021, taken in the above-captioned case.

9. Attached hereto as **Exhibit 7** is a copy of documents produced in the above-captioned case with Bates No. AMK-CCPD-Records-000013.

10. Attached hereto as **Exhibit 8** is a copy of the deposition transcript of Jody Fedler, dated July 25, 2022, taken in the above-captioned case.

11. Attached hereto as **Exhibit 9** is a copy of documents produced in the above-captioned case with Bates No. R000056.

12. Attached hereto as **Exhibit 10** is a copy of documents produced in the above-captioned case with Bates No. AMK-CSHCC-S-MD-000004-000008.

13. Attached hereto as **Exhibit 11** is a copy of the deposition transcript of Ray Fernandez, M.D., dated July 28, 2022, taken in the above-captioned case.

14. Attached hereto as **Exhibit 12** is a copy of documents produced in the above-captioned case with Bates No. AMK-CCPD-Photos-000470-000483.

15. Attached hereto as **Exhibit 13** is a copy of documents produced in the above-captioned case with Bates No. AMK-CCPD-Records-000029.

16. Attached hereto as **Exhibit 14** is a copy of the expert report of Erin M. Mannen, Ph.D., dated July 11, 2022, taken in the above-captioned case.

17. Attached hereto as **Exhibit 15** is a copy the 2019 U.S. Consumer Product Safety Commission study, produced in the above-captioned case, with Bates Nos. KELLY-000065-000141.

18. Attached hereto as **Exhibit 16** is a copy the hearing transcript in the above-captioned case on August 55, 2022.

19. Attached hereto as **Exhibit 17** is a copy of Wang, J. *et al.*, “Infant inclined sleep product safety: A model for using biomechanics to explore safe infant product design,” *Journal of Biomechanics* (Aug. 23, 2021).

20. Attached hereto as **Exhibit 18** is a copy of AAP Policy Statement, *SIDS and Other Sleep-Related Infant Deaths: Expansion of Recommendations for a Safe Infant Sleeping Environment* (2011).

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed this 13th day of February, 2023 in Houston, Texas.

/s/ Mary-Olga Lovett
Mary-Olga Lovett